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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/606,137 | 06/25/2003 | David Vincent Zyzak | 9043MXL | 3971 |

27752 7590 02/23/2005

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
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EXAMINER

HENDRICKS, KEITH D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1761

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,137

Applicant(s)

ZYZAK ET AL.

Examiner

Keith Hendricks

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-32 and 45-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "reduced", in product claims 11-32 and 45-50, is a relative term which renders the claim indefinite. The term "reduced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicant's arguments filed December 02, 2004, have been fully considered but they are not persuasive. At pages 6-7 of the response, applicants state that the term "reduced" is well known and sufficiently defined, especially in light of the specification. This is not deemed persuasive, as the actual *definition* of the term is not in question. The Examiner agrees with applicant as to the meaning of the term.

At page 7 of the response, applicant states that "applicants respectfully assert that one skilled in the art would understand that the use of the term 'reduced' in the present claims describes the level of asparagine or acrylamide in treated food material as compared to the level present in untreated food material." This is not deemed persuasive for the reasons of record. In this instance, applicant has supplemented the definition of the term "reduced", with context and essential information such that one skilled in the art would actually recognize and understand the metes and bounds of the claimed invention. However, this phrasing does not appear in the claims, and the context of the claims and the term "reduced" is not clear, in light of the specification. While the specification may be useful to clarify or support the claims, it is improper to rely upon the specification to provide the role of distinctly claiming the subject matter which the applicant regards as their invention. It is unclear why applicant refuses to clarify the *claimed invention* by this means. As previously stated on the record, the term "reduced" necessarily indicates both a current condition and a previous condition, as well as a change from the previous to the current state. These conditions must be provided in the context of a claim, in order to establish the necessary properties and in order to understand how the term "reduced" applies in this

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context. A product, as it stands in its current state, cannot simply be "reduced", without reference to a standard or to the previous condition. Applicants, in their attempt to demonstrate support for the claimed term, even rely upon this fact.

Further, as an example, if a simple box contained five beans, it would be impossible to discern whether this amount was "reduced" from a previous higher number of beans, or even "increased" from a lower number, or had always possessed five beans. A simple label of "reduced" would not be sufficient to describe the box which originally had, say, ten beans, without proper context (and also would not differ from a box which always possessed five beans). The same principle applies to a final food product, including potato products, as instantly claimed. Thus similarly, if two distinct cooked potato crisps each contain 350 ppb of acrylamide, where one naturally contained said amount and one had been processed according to the invention, given this data alone, it would be impossible for one skilled in the art to determine which one had been "reduced" from a previously higher amount, and which one was naturally at this level.

Examiner Notes:

(1) Regarding the issue concerning an "asparaginase reducing enzyme", this has been withdrawn in light of applicant's arguments. It is noted that applicant has referred to the definition provided in the specification, which will be used from here forth.

(2) Regarding the term "low", as used in claims 46 and 48, this has been withdrawn in light of applicant's arguments. It is noted that applicants have stated at page 9 of the response, that "because the presently rejected claims relate only to the labeling of the product, rather than the potato products [i.e. food material], it is irrelevant what the term 'low' actually means in these claims."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Elder et al. (Pub. No. US 2004/0058054).

Applicant's arguments filed December 02, 2004, have been fully considered but they are not persuasive. At page 10 of the response, applicant states that

with regard to this obviousness rejection, Applicants respectfully disagree with the Examiner and assert that Elder '054 not only does not teach or suggest Applicants' invention but also fails to provide a reasonable expectation of success between its examples, particularly example no. 5, and the claimed subject matter of Elder '054, namely reducing the presence of acrylamide in thermally processed food. In so doing, Elder '054 has failed to appreciate the difficulty in adding or applying an asparagine-reducing enzyme to food.

Applicant states that with regard to the Elder reference, "one is struck by the fact that the reduction of either asparagine or acrylamide is never achieved in food."

Also, at page 11 of applicant's response, applicant asserts that the reference discloses that "asparaginase can be used to come into 'contact' with the simple sugar/amino acid combination. Other than putting asparaginase in the test tubes of Example No. 5, the nature of this 'contact' is never explained, defined or taught. Applicants' 'contact' of their asparagine-reducing enzyme is much more robust and definitive." Further, applicant states that "such detailed addition is necessary because of the nature of food, and in particular potato products which have a cellular structure that is difficult to either break-down or weaken and penetrate with an enzyme or any other substance."

This is not deemed persuasive for the reasons of record. Despite the fact that the reference discloses a method for reducing the amount of acrylamide in thermally processed foods, and despite the fact that the reference specifically states that thermally processed foodstuffs which originally contained asparagine tested positive for acrylamide, and finally, despite the fact that the reference specifically states that "one such method for inactivating [asparagine] is to contact asparagine with the enzyme asparaginase", applicant alleges that there is no suggestion or motivation in the reference for one of ordinary skill in the art to reduce the level of asparagine – and thus the level of acrylamide in food materials – by adding asparaginase to food materials. This is simply not deemed persuasive, and appears to fly in the face of the teachings and spirit of the reference. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention *without specifically pointing out how the language of the claims patentably distinguishes them from the reference*. Applicant has stated that "Elder '054 has failed to appreciate the difficulty in adding or applying an asparagine-reducing enzyme to food", yet this is not reflected in the instant claim language. Applicant states that "one is struck by the fact that the reduction of either asparagine or acrylamide is

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never achieved in food.” However, a food product such as a potato crisp or any other foodstuff, is simply a composition, just as the test tube experiments of Elder et al. also utilize compositions. All of the necessary components are present in both compositions, and thus one of ordinary skill in the art would have expected the teachings of Elder et al. to function, absent any clear and convincing evidence and/or arguments to the contrary. If the addition of an enzyme to a composition involves complex maneuvers and is such difficult task, then applicant’s claims should reflect this. In response to applicant’s argument that the references fail to show certain features of applicant’s invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant’s claims do not reflect any such “robust and definitive... detailed addition” of the enzyme. Furthermore, it is noted that page 4 of applicant’s own specification, as quoted by applicant in the footnote of page 11 of the response, states that “the enzyme may be added to the food material in any suitable form. For instance, the enzyme may be added as a powder or in the form of a solution. Furthermore, *the enzyme may be added to the food material in any suitable manner, such as directly (for example, sprinkled, poured, or sprayed on the food material) or indirectly.*” (emphasis added). Thus, it is clear that the breadth of applicant’s claims specifically encompasses the suggested mode of adding asparaginase to a food product, as taught by the reference.

Contrary to that which applicant alleges, it is unclear to the Office as to how one skilled in the art might read the reference as a whole, and *not* come away with the direct teaching that in order to inactivate asparagine within a food product, and thus provide a food product with less acrylamide formation than one which has not been treated, the food product may be treated with asparaginase. As previously stated on the record, and directly quoted from the reference, “one such method for inactivating is to contact asparagine with the enzyme asparaginase. This enzyme decomposes asparagine to aspartic acid and ammonia” (par. 0011). This reaction was performed in Example 5, where it is demonstrated that such treatment “with an enzyme that decomposes asparagine to aspartic acid and ammonia reduced acrylamide formation by more than 99.9%. *This experiment establishes that reducing the concentration of asparagine, or the reactive nature or [‘of’; sic] asparagine, will reduce acrylamide formation.*” Thus, this direct teaching, suggestion and actual example set forth in the reference, would clearly provide the necessary motivation, guidance and reasonable expectation of success to the ordinarily-skilled artisan in order to utilize the protocol with the specifically-recited food items, including potato products, absent any clear and/or convincing arguments to the contrary. In fact, it is unclear as to what different or contrary

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conclusions might be drawn from the teachings of the reference. Applicant has not sufficiently distinguished the claimed invention from the teachings of the reference.

Regarding applicant's statement that there is no teaching of all the claim limitations because "Elder fails to teach a method of reducing the level of asparagine/acrylamide in food," this is not deemed persuasive for the reasons of record. As applicants themselves have stated, it is noted that the test for obviousness is not whether the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the reference(s) would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Applicant is correct in stating that the reference does not specifically teach, i.e. provide an example of, reducing the level of asparagine/acrylamide in foodstuffs, *per se*. However, as stated above and previously on the record, the reference clearly and unambiguously suggests to one of ordinary skill in the art, the instantly-claimed method of utilizing an asparaginase enzyme for inactivating asparagine in a food material, including potato products, thereby reducing the level of acrylamide which would be formed in the subsequently heated food material. The reference leaves no question as to whether this would prove successful with regard to the recited food products, as this is the primary purpose and goal of the reference.

Furthermore, it is noted that several of applicant's claims recite the phrase "food material." Within the context of prior art issues, it is unclear as to what is, and is not, encompassed by this phrase. However, it may be reasonably asserted that "a food material" includes that which makes up a final food product, and as such, would inherently include the glucose and asparagine composition system of example 5 of Elder et al. Regarding applicant's assertion that "there is no showing that such an example is in any way representative of what would occur if the method disclosed therein was carried out using an actual food product" (pg. 12, response), at paragraph 0012 of Elder et al it is stated that "with lower levels of asparagine in the food ingredient or the food product prior to thermal processing, the level of acrylamide in the final processed food will be dramatically reduced." Given the fact that food materials and food products are simply chemical compositions themselves, the referenced process would have reasonably been expected to function similarly across multiple food products, including corn chips, potato chips & crisps, and tortillas, each of which contain free asparagine which would otherwise have been converted to acrylamide in the heating process.

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Double Patenting – Non-statutory

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

i) Claims 45-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-12 of copending Application No. 10/606,260.

ii) Claims 1-32 and 42-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 10/603,279.

iii) Claims 11-44 and 47-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/603,978.

iv) Claims 1-20, 22-31 and 45-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57 of copending Application No. 10/603,973.

v) Claims 1-20, 22-31 and 45-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-18 of copending Application No. 10/603,278.

Applicant's arguments filed December 02, 2004, have been fully considered but they are not persuasive. At page 12 of the response, applicant states that the copending claims fail to teach or suggest the instantly claimed invention. This is not deemed persuasive for the reasons of record. Applicant's instant claims are broadly recited to include several food items, methods and containers for such, wherein

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the food item possesses a "reduced level of acrylamide." As previously explained on the record with regard to each individual copending application, this directly encompasses and renders obvious the copending claimed inventions, directed to a food item (cocoa beans, snack chips, etc.), methods and containers for such, wherein the food item possesses a "reduced level of acrylamide."

Conclusion


Applicant's amendment (of claim 6) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


KEITH HENDRICKS
PRIMARY EXAMINER